

117TH CONGRESS
1ST SESSION

S. 415

To amend the Federal Food, Drug, and Cosmetic Act with respect to the scope of new chemical exclusivity.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 24, 2021

Mr. CASSIDY (for himself, Ms. SMITH, and Mr. MARSHALL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the scope of new chemical exclusivity.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. CLARIFYING THE MEANING OF NEW CHEMICAL**
4 **ENTITY.**

5 (a) IN GENERAL.—Chapter V of the Federal Food,
6 Drug, and Cosmetic Act is amended—

7 (1) in section 505 (21 U.S.C. 355)—

8 (A) in subsection (c)(3)(E), by striking

9 “active ingredient (including any ester or salt of

10 the active ingredient)” each place it appears

1 and inserting “active moiety (as defined by the
2 Secretary in section 314.3 of title 21, Code of
3 Federal Regulations (or any successor regula-
4 tions))”;

5 (B) in subsection (j)(5)(F), by striking
6 “active ingredient (including any ester or salt of
7 the active ingredient)” each place it appears
8 and inserting “active moiety (as defined by the
9 Secretary in section 314.3 of title 21, Code of
10 Federal Regulations (or any successor regula-
11 tions))”;

12 (C) in subsection (l)(2)(A)—

13 (i) by amending clause (i) to read as
14 follows:

15 “(i) not later than 30 days after the date
16 of approval of such applications—

17 “(I) for a drug, no active moiety (as
18 defined by the Secretary in section 314.3
19 of title 21, Code of Federal Regulations (or
20 any successor regulations)) of which has
21 been approved in any other application
22 under this section; or

23 “(II) for a biological product, no ac-
24 tive ingredient of which has been approved
25 in any other application under section 351

1 of the Public Health Service Act; and”;
 2 and

3 (ii) in clause (ii), by inserting “or bio-
 4 logical product” before the period;

5 (D) by amending subsection (s) to read as
 6 follows:

7 “(s) REFERRAL TO ADVISORY COMMITTEE.—The
 8 Secretary shall—

9 “(1) refer a drug or biological product to a
 10 Food and Drug Administration advisory committee
 11 for review at a meeting of such advisory committee
 12 prior to the approval of such drug or biological if it
 13 is—

14 “(A) a drug, no active moiety (as defined
 15 by the Secretary in section 314.3 of title 21,
 16 Code of Federal Regulations (or any successor
 17 regulations)) of which has been approved in any
 18 other application under this section; or

19 “(B) a biological product, no active ingre-
 20 dient of which has been approved in any other
 21 application under section 351 of the Public
 22 Health Service Act; or

23 “(2) if the Secretary does not refer a drug or
 24 biological product described in paragraph (1) to a
 25 Food and Drug Administration advisory committee

1 prior to such approval, provide in the action letter
 2 on the application for the drug or biological product
 3 a summary of the reasons why the Secretary did not
 4 refer the drug or biological product to an advisory
 5 committee prior to approval.”; and

6 (E) in subsection (u)(1), in the matter pre-
 7 ceding subparagraph (A)—

8 (i) by striking “active ingredient (in-
 9 cluding any ester or salt of the active in-
 10 gredient)” and inserting “active moiety (as
 11 defined by the Secretary in section 314.3
 12 of title 21, Code of Federal Regulations (or
 13 any successor regulations))”; and

14 (ii) by striking “same active ingre-
 15 dient” and inserting “same active moiety”;

16 (2) in section 512(c)(2)(F) (21 U.S.C.
 17 360b(c)(2)(F)), by striking “active ingredient (in-
 18 cluding any ester or salt of the active ingredient)”
 19 each place it appears and inserting “active moiety
 20 (as defined by the Secretary in section 314.3 of title
 21 21, Code of Federal Regulations (or any successor
 22 regulations))”;

23 (3) in section 524(a)(4) (21 U.S.C.
 24 360n(a)(4)), by amending subparagraph (C) to read
 25 as follows:

1 “(C) is for—

2 “(i) a human drug, no active moiety
3 (as defined by the Secretary in section
4 314.3 of title 21, Code of Federal Regula-
5 tions (or any successor regulations)) of
6 which has been approved in any other ap-
7 plication under section 505(b)(1); or

8 “(ii) a biological product, no active in-
9 gredient of which has been approved in any
10 other application under section 351 of the
11 Public Health Service Act.”;

12 (4) in section 529(a)(4) (21 U.S.C.
13 360ff(a)(4)), by striking subparagraphs (A) and (B)
14 and inserting the following:

15 “(A) is for a drug or biological product
16 that is for the prevention or treatment of a rare
17 pediatric disease;

18 “(B)(i) is for such a drug—

19 “(I) that contains no active moiety (as
20 defined by the Secretary in section 314.3
21 of title 21, Code of Federal Regulations (or
22 any successor regulations)) that has been
23 previously approved in any other applica-
24 tion under subsection (b)(1), (b)(2), or (j)
25 of section 505; and

1 “(II) that is the subject of an applica-
 2 tion submitted under section 505(b)(1); or
 3 “(ii) is for such a biological product—

4 “(I) that contains no active ingredient
 5 that has been previously approved in any
 6 other application under section 351(a) or
 7 351(k) of the Public Health Service Act;
 8 and

9 “(II) that is the subject of an applica-
 10 tion submitted under section 351(a) of the
 11 Public Health Service Act;” and

12 (5) in section 565A(a)(4) (21 U.S.C. 360bbb–
 13 4a(a)(4)), by amending subparagraph (D) to read as
 14 follows:

15 “(D) is for—

16 “(i) a human drug, no active moiety
 17 (as defined by the Secretary in section
 18 314.3 of title 21, Code of Federal Regula-
 19 tions (or any successor regulations)) of
 20 which has been approved in any other ap-
 21 plication under section 505(b)(1); or

22 “(ii) a biological product, no active in-
 23 gredient of which has been approved in any
 24 other application under section 351 of the
 25 Public Health Service Act.”.

1 (b) TECHNICAL CORRECTIONS.—Chapter V of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
3 et seq.) is amended—

4 (1) in section 505 (21 U.S.C. 355)—

5 (A) in subsection (c)(3)(E), by repealing
6 clause (i); and

7 (B) in subsection (j)(5)(F), by repealing
8 clause (i); and

9 (2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C.
10 355a(c)(1)(A)(i)(II)), by striking “(c)(3)(D)” and
11 inserting “(c)(3)(E)”.

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